REMARKS

Claims 58-67 are pending. Claims 62 and 67 have been canceled without prejudice. No issue of new matter is raised by these amendments. Accordingly, claims 58-61 and 63-66 will be pending in the subject application upon entry of this Amendment.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the November 17, 2004 Final Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

The Claimed Invention

The instant invention provides a method and a kit for predicting pregnancy outcome. This invention is based upon the surprising discovery of a correlation between pregnancy outcome and the ratio of urinary levels of the early pregnancy-associated molecular isoform of hCG to intact hCG.

Double Patenting Rejection

The Examiner rejected claims 58-67 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53, 59, 60, 65, 71, 72, and 77-82 of U.S. Serial No. 09/017,976, now U.S. Patent No. 6,500,627, for the reasons of record.

In response, applicants will consider submitting a terminal disclaimer at such time as the instant claims are deemed otherwise allowable.

Rejection under 35 U.S.C. §102(e)

The Examiner rejected claims 62 and 67 under 35 U.S.C. §102(e) as allegedly anticipated by Cole et al. (U.S. Patent No. 6,429,018; "Cole").

In response, applicants note that claims 62 and 67 have been canceled, rendering the rejection thereof moot.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 58-61 under 35 U.S.C. §103(a) as allegedly unpatentable over Cole in view of Birken et al. (Endocrinology, 1993)("Birken").

In response, applicants respectfully traverse.

Claims 58-61 provide a method for predicting pregnancy outcome in a subject. Specifically, these claims provide a method comprising the step of detecting the *ratio* of EMPI-hCG to intact hCG in a sample, wherein a ratio greater than 1 indicates a positive pregnancy outcome, and a ratio less than 1 indicates a negative pregnancy outcome.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three things with respect to each claim. First, the cited references, when combined, must teach or suggest each element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

Applicants maintain that the cited references fail to support a *prima facie* case of obviousness because they do not teach or suggest every element of the claimed invention. That is, the cited references fail to teach or suggest a method for predicting pregnancy outcome in a subject by determining the *ratio* of EPMI-hCG to intact hCG in a sample. Moreover, these references, when combined, also fail to teach or suggest a ratio of 1 as the number above which a positive pregnancy outcome is indicated.

Thus, the cited references combined fail to teach every element of the rejected claims. The Examiner has not provided evidence to the contrary. Thus, the Examiner has failed to establish a *prima facie* case of obviousness.

The Examiner also rejected claims 63-66 under 35 U.S.C. §103(a) as allegedly unpatentable over Cole, in view of Birken, and in further view of Foster et al. (U.S. Patent no. 4,444,879).

In response to the Examiner's rejection, applicants respectfully traverse.

Claims 63-66 provide a diagnostic kit for predicting pregnancy outcome in a subject comprising antibodies which bind to EPMI-hCG and antibodies which bind to intact hCG.

Applicants maintain that the cited references, in combination, fail to teach or suggest the notion that the ratio of EPMI-hCG to intact hCG can indicate a positive or negative pregnancy outcome. Absent this teaching, the Examiner has not set forth a proper basis for concluding that a kit useful for detecting such a ratio would have been obvious.

In view of the above remarks, applicants maintain that claims 58-61 and 63-66 satisfy the requirements of 35 U.S.C. §103(a).

November 4, 2004 Examiner's Interview

On November 4, 2004, Examiner Gabel had a telephonic interview with applicants' attorney, John P. White, Esq. Applicants wish to thank Examiner Gabel for her time and consideration during the interview.

Examiner Gabel notified Mr. White that the July 12, 2004 Office Action should have properly been a Non-Final Action since new grounds of rejection were introduced and that Applicant's October 14, 2004 Communication in response should be a response to a Non-Final Action.

Applicants acknowledge the Examiner's comments and note that the instant Amendment is properly in response to a Final Office Action. Applicants further note that this statement of the substance of the interview is considered timely because it is filed together with a reply to the last Office Action.

Summary

In view of the remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the $510.00 extension fee, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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